PATENT SPECIFICATION
NO DRAWINGS ATTACHED

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COMPLETE SPECIFICATION

# Protective Dressings

We, E. R. SQUIBB & SONS, INC., a corporation organised and existing under the laws of the State of Delaware, United States of America, of 745, Fifth Avenue, New York, State of New York, United States of America, do hereby declare the invention, for which we pray that a patent may be granted to us, and the method by which it is to be performed to be particularly described in and by the following statement:—

This invention relates to protective dressings, and more particularly, to protective dressings which may be applied to moist body surfaces such as those of the oral cavity and remain adhered thereto over extended periods of time.

Heretofore, there has not been available to dentists, dental surgeons, dermatologists and other like practitioners of the medical art any dressings which could be used locally on body surfaces both internal and external, either moist or dry, over extended periods of time. Attempts to employ special tape or other like dressings on moist body surfaces especially, have universally met with failure. The moisture encountered upon application prevents adherence of the tape. Attempts to overcome these shortcomings by the use of ointments or other like substances have likewise met with failure, due to the fact that the moisture present shortly causes the ointments and other like substances to be washed away.

It has now been found possible to prepare a dressing which will adhere to body surfaces and notably on moist body surfaces including moist surfaces of the oral cavity. These dressings are soft, pliable, and easy to apply, and when applied, conform to the curvature of the surface upon which they are applied, and especially in the case of application to the internal surface of the oral cavity. The dressing of this invention has no odor or taste, and once it is applied to the surface to be treated, it will not of itself peel off, chip off and fall off, but slowly wear off over an extended period of time. The dressing of this invention will remain in position through all activities of the person being treated, for example, during drinking, eating, sleeping, speaking, chewing or biting, without any signs of irritation or toxicity.

In addition to their unique adhering properties, the dressings of this invention have been found to promote the healing of the areas treated therewith. The use of the dressings, of this invention have been found to reduce the time for healing from days to hours in some cases of intra-oral use.

According to the present invention there is provided a protective dressing comprising a sheet of plastic adhesive material comprising a blend of a water soluble or water swellable hydrocolloid and a water insoluble, viscous elastic binder.

According to a further feature of the invention there is provided a process for preparing a protective dressing comprising mixing a water soluble or water swellable hydrocolloid and a water insoluble viscous elastic binder to produce a plastic, adhesive mix-

ture and shaping the mixture to the form of a sheet.

The adhesive materials used in accordance with this invention may comprise, as the water soluble or swellable hydrocolloid, polyvinyl alcohol, powdered pectin, gelatin, carboxymethylcellulose, high molecular weight polyethylene glycol i.e. the solid type of material sold under the Trademark "Carbowax" or carboxypolymethlene or a mixture of two or more of these substances and the viscous elastic binder may be a natural or synthetic gum-like substance such as natural rubber, silicone rubber, acrylonitrile rubber, polyurethane rubber, polyisobutylene, and sucrose acetate isobutylate or a mixture of such substances. The viscous elastic binder binds the hydrocolloid and, in addition, renders the blend elastic and pliable. It has been found that the use of polyisobutylene, having incorporated therein a powdered mixture of pectin, gelatin, and carboxymethylcellulose, gives a most satisfactory adhesive material.

In conjunction with the natural or synthetic binders employed in the practice of this invention, it may be desirable to employ plasticisers or solvents, such as mineral oil or petrolatum in combination therewith, to improve adherence characteristics and/or to provide the desired consistency.

In addition to the use of sheets of the adhesive material of this invention by themselves, it has been found that very satisfactory results are obtainel when a thin, pliable water impervious and preferably water insoluble, backing film is secured to one side of a sheet of the adhesive material. The water impervious backing films which may be employed in the practice of this invention include *inter alia* water insoluble films prepared from such materials as polyethylene, polymers and copolymers of vinylidene chloride, condensation products of ethylene glycol and terephthalic acid and polypropylene. Most preferably, we employ a polyethylene film in the practice of this invention, although the other water impervious films also give satisfactory results.

In the practice of this invention, medicaments may be applied and retained on the affected areas on the body surfaces to be treated by the employment of the novel dressings of this invention. For these purposes, the medicament may be applied on the surface of the dressing that will come in contact with the affected area to be treated or may be incorporated in the adhesive composition from which the dressing is made. The medicament may be applied to the surface of the dressing as by dusting, spraying or spreading. Among the medicaments which may be employed are included such substances as insulin, antibiotics, for example, amphoterecin, tetracycline; anaesthetics, such as benzocaine; anti-inflammatories, such as triamcinolone acetonide.

The water impervious film which may be employed in the practice of this invention may have a thickness of from 0.0005 inches to 0.05 inches and most preferably from 0.0005 to 0.002 inches. The adhesive material to one surface of which the impervious backing film is applied, is in sufficient amount to give a complete coverage of the wounded area to be treated. It has also been found that it is possible to apply a water impervious backing film to the dressings of this invention after they have been placed on the surface being treated.

The size and thickness of the sheet of adhesive material depends on the area to be treated and the duration of application desired.

The thickness of the individual sheet of plastic adhesive material will of necessity determine the length of duration of application of the dressing. The thinner the sheet, the shorter the duration of application. In other words, the thinner the sheet, the less time it takes to naturally disperse.

In the practice of this invention, it is preferred to use a sheet of plastic adhesive material having a thickness from 0.0001" to 0.01" although, the choice of the thickness for the sheet may be left to the skilled artesan. In the embodiment of this invention wherein a water insoluble backing is employed, the water insoluble backing acts to retard the rate of dispersion of the sheet of adhesive material.

In the practice of this invention the novel dressings of the invention may be cut to the proper size to completely cover the affected area being treated. The dressing may then merely be placed on this area, the natural moisness thereof causing the adhesive material to adhere to the affected area. In the case where a water impervious backing material is employed on one surface, the dressing remaining after the desired length of treatment may be easily removed and discarded and a new dressing of the same type employed as a replacement. The invention is illustrated by the following examples:

EXAMPLE 1.

Fifty-eight grams of polyisobutylene are heated to 70—80° C. Forty-two grams of a mixture of pectin, gelatin, and sodium carboxymethylcellulose is then mixed in with the heated polyisobutylene and the mixture allowed to cool, thereby forming a plastic dough-like substance. Ths dough-like substance is passed through a roller mill to make the mixture more uniform, and the dough is then flattened in a hydraulic press to form a sheet of the desired thickness. A sheet of thin gauge polyethylene film is then pressed over one side and the resultant mat is cut

into strips, squares or other shapes of dressing of the desired size.

EXAMPLE 2

The process of Example 1 is followed except that instead of 58 grams of polyisobutylene, there is substituted a mixture of 56 grams of polyisobutylene and 2 grams of petrolatum. A satisfactory dressing is thus obtained.

EXAMPLE 3

The procedure of Example 1 is followed except that instead of the 58 grams of polyisobutylene, there is substituted a mixture of 55 grams of polyisobutylene and 1 gram of mineral oil, which mineral oil has been preheated to 70—80° C. A satisfactory dressing is thus obtained

EXAMPLE 4

The procedure of Example 1 is followed except that 42 grams of polyvinylalcohol fine powder is substituted for the 42 grams of the mixture of pectin, gelatine, and sodium carboxymethylcellulose.

EXAMPLE 5

The procedure of Example 1 is followed except that 42 grams of gum acacia is substituted for the mixture of pectin, gelatin, and sodium carboxymethylcellulose.

EXAMPLE 6

The procedure of Example 1 is followed except that a mixture of 30 grams of gum acacia and 12 grams of a powdered mixture of gelatin, pectin, and sodium carboxymethylcellulose is employed. This powdered mixture is substituted for the 42 grams of the mixture of pectin, gelatin and sodium carboxymethylcellulose to yield a satisfactory dressing.

EXAMPLE 7

The procedure of Example 1 is followed except that a mixture of 37 grams of a mixture of pectin, gelatin and carboxymethylcellulose is combined with 5 grams of benzocaine prior to the addition of the polyisobutylene to yield a medicated dressing.

EXAMPLE 8

The procedure set forth in Example 1 is followed except that a mixture of 38 grams of pectin, gelatin, sodium carboxymethylcellulose and 3 grams of amphotericin B and 1 gram of tetracycline base is employed in place of the powdered mixture of gelatin, pectin and carboxymethylcellulose to yield the medicated dressing.

EXAMPLE 9

The procedure set forth in Example 1 is followed except that no polyethylene film is applied to the flattened mass of dough-like adhesive composition. The resulting dressing can be applied directly to the surface being treated.

EXAMPLE 10

The procedure set forth in Example 1 is followed except that a mixture of 39 grams of pectin, gelatin, sodium carboxymethyl-cellulose and 3 grams of insulin is employed in place of the powdered mixture of gelatin, pectin and carboxymethylcellulose to yield the desired medicated dressing.

EXAMPLE 11

The procedure of Example 1 is followed except that 22 grams of sucrose acetate isobutyrate is substituted for the polyisobutylene and 33 grams of a powdered mixture of pectin, gelatin and sodium carboxymethylcellulose is employed. A sheet of the resultant adhesive composition may then be employed directly as a dressing or a water insoluble polyethylene film may be applied to one surface of the sheet prior to use.

EXAMPLE 12

The procedure of Example 1 is followed except that a film of polymeric fluorine-containing halogenated hydrocarbon is employed in place of the polyethylene film.

WHAT WE CLAIM IS:—

1. A protective dressing comprising a sheet of plastic adhesive material comprising a blend of a water soluble or water swellable hydrocolloid and a water insoluble, viscous elastic binder.

2. A dressing as claimed in Claim 1 wherein one surface of the sheet is provided with a backing film of water impervious material.

3. A dressing as claimed in either of Claims 1 or 2 wherein the hydrocolloid is polyvinyl alcohol, gum acacia, pectin, gelatin, carboxymethylcellulose, sodium carboxymethylcellulose, high molecular weight polyethylene glycol or carboxypolymethylene or a mixture of two or more thereof.

4. A dressing as claimed in any preceding Claim wherein the viscous elastic binder is natural rubber, silicone rubber, acrylonitrile rubber, polyurethane rubber, polyisobutylene or sucrose acetate isobutyrate.

5. A dressing as claimed in Claim 2 wherein the adhesive material contains about 58% by weight of binder.

6. A dressing as in any preceding Claim wherein the hydrocolloid is a mixture of pectin gelatin and carboxymethylcellulose and the binder is polyisobutylene.

7. A protective dressing for use in the oral, cavity comprising a thin polyethylene backing film and adhering to one side thereof a sheet of plastic adhesive material comprising a smooth blend of about 58% by weight of polyisobutylene and about 42% by weight of a mixture of pectin, gelatin and sodium carboxymethylcellulose.

8. A protective dressing substantially as

hereinbefore described with reference to any one of the examples.

9. A process for preparing a protective dressing comprising mixing a water soluble or water swellable hydrocolloid and a water insoluble viscous elastic binder to produce a pastic, adhesive mixture and shaping the mixture to the form of a sheet.

10. A process as claimed in Claim 9 which includes adhering a water impervious backing film to one surface of the sheet.

11. A process as claimed in either of Claims 9 or 10 wherein the hydrocolloid is gum acacia, a polyvinyl alcohol, pectin, gelatin, carboxymethylcellulose, high molecular weight polyethylene glycol, or carboxypolymethylene or a mixture of one or more thereof.

12. A process as claimed in any of Claims 9 to 11 wherein the viscous, elastic binder is natural rubber, silicone rubber, acrylonitrile rubber, polyurethane rubber, polyisobutylene, or sucrose acetate isobutylate.

13. A process as claimed in any of claims 9 to 12 which includes the use of solvents or plasticizers.

14. A process as claimed in Claim 9 which includes heating polyisobutylene to a temperature between 70—80° C., adding thereto a mixture of pectin, gelatin, and sodium carboxymethylcellulose, cooling and forming the mixture into a sheet, adhering a polyethylene film to one side of the sheet and cutting the sheet into strips.

15. A process as claimed in any of Claims 9 to 14 which includes incorporating a medicament in the dressing.

16. A process for preparing a protective dressing substantially as hereinbefore described with reference to the Examples.

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